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09/554,414	09/06/2000	Moshe Szyf	2055MC/48896	9016

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EXAMINER

WALICKA, MALGORZATA A

ART UNIT PAPER NUMBER

1652

DATE MAILED: 10/17/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/554,414

Applicant(s)

SZYF ET AL.

Examiner

Malgorzata A. Walicka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) \_\_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 19-25 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Reply to Office Action filed on August 9, 2002, as paper No. 15, is acknowledged.

### **Office Action**

#### **1. Response to Applicants traverse**

Applicant's election with traverse of claims 19-25 of Group XIII, in Paper No. 15, is acknowledged. The traversal is on the ground(s) presented below.

Firstly, the Applicants state: "The restriction requirement is procedurally defective in that it does not discuss the presence or absence of 'corresponding special technical features'. On the contrary, the only discussion in the restriction requirement appears to relate to the standards of 'independence' and 'distinctness', which apply to regular U. S. utility applications."

Secondly, Applicants opinion is: "The Office Action errs in stating that 37 C. F. R. §1.475 does not provide for multiple products or methods within a single application. 37 C.F.R. §1.475 (c) states:

'If an application contains claims to more or less than one of the combination and categories of inventions set forth in paragraph (b) of this section, unity of invention **might** not be present. (emphasis supplied)'

The use of the conditional word 'might' in subparagraph (c) of Rule 1. 475 clearly indicates that the presence of claims to more or less than one of the combinations recited in subsection (b) does not necessarily establish that unity of invention is present.

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Thus, it is possible to have unity of invention with multiple products or methods, **so long as the claims all have corresponding technical features** [emphasis added, MW]."

Thirdly, "It is also instructive that neither the International Searching Authority, nor the International Preliminary Examining Authority, both of which are required to review and make a determination regarding the presence or absence of unity of invention, found unity of invention to be lacking."

Applicants arguments have been fully considered, but they are found not persuasive for the following reasons.

Regarding the first argument, the restriction requirement of the previous Office Action, paper No. 14, fails to emphasize lack of special technical feature of claims 1-30 of the instant application. However, International Preliminary Report and International Search Report, provided evidence that DNA molecules of SEQ ID NO:1, 3, 5 and 7 encoding claimed proteins of SEQ ID NO:2, 4, 6 and 8 are identical to polynucleotides registered on Oct. 28, 1998 with nucleotide accession number AF072242, AF072243, AF072247, AF072248, respectively. The amino acid sequences deduced from them are 100% identical to SEQ ID NO: 2, 4, 6 and 8 of the claimed proteins; see the International Preliminary Search Report. The sequences were then published on November 11, 1999, by Hendrich et al, in "Identification and Characterization of a family of Mammalian Methyl-CpG Binding proteins" (*Molecular and Cellular Biology*, Nov. 1998, 6538-6547). The priority to Canadian Patent Applications No. 2,220,805, filed

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11/12/1997; and 2,230,991, filled 05/11/1998, claimed by the Applicants is not granted, because none of the Canadian Applications discloses SEQ ID NOs: 2, 4, 6, and 8 and their encoding DNA molecule of SEQ ID NOs: 1, 3, 5, and 7; see also the International Preliminary Search Report. Thus, the effective filling date of the instant application is the filling date of the PCT application No. PCT/CA98/01059, which is 11/12/98. In the light of these facts proteins of SEQ ID NOs: 2, 4, 6, and 8 do not constitute the contribution over the prior art. For that reason, claims 1-30 of the instant application do not share the same or corresponding technical feature and unity of invention is lacking with respect to these claims.

In conclusion, the instant application contains inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1, and restriction under 35 U.S.C. 121 and 372 is proper.

With regard to the third argument, the examiner of the U.S. national stage of the PCT application is not bound by the opinion of the application examiners at the international stage. Both PCT International Preliminary Examination Report and PCT International Search Report do not indicate, or comment on, lack of unity of invention in the instant application. However, both these documents provide evidence for lack of the unity as indicated above.

Regarding the second argument, the Office Action does not err in stating that 37 C. F. R. §1.475 does not provide for multiple products or methods within a single

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application. As Applicants indicate, the conditional form "might" used in 37 C.F.R. §1.475 (c) allows for both interpretation of the rule, i.e. lack of unity of invention, as well as its presence "so long as the claims all have corresponding technical features". As discussed above, claims 1-30 of the instant application do not have corresponding technical features because the feature is not a contribution over the prior art. The considered statement of the previous Office Action is, therefore, correct.

## **2. Supplemental restriction requirement**

Upon review of all claims and specification of the instant application, as well as the priority documents, PCT International Preliminary Examination Report, PCT International Search Report and Information Disclosure Statement, the additional restriction within the elected Group XIII is required. The examiner regrets any inconvenience that may cause.

Restriction within Group XIII, claims 19-25, elected in paper No. 15, is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group XIII-1, claim(s) 19-22 (partially), drawn to use of antagonist or inhibitor of human

DNA demethylase of SEQ ID NOs: 2 and 4 for the manufacture of a medicament for cancer treatment.

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Group XIII-2, claims(s) 19-22 (partially), and 23-25, drawn to the use of an antagonist or inhibitor of the human DNA demethylase of SEQ ID NOs: 2 and 4, for restoring an aberrant methylation pattern in a patient DNA, or for changing a methylation pattern in the patient DNA.

Groups XIII-1 and XIII-2 lack unity of invention because they do not share corresponding special technical feature. The DNA methylases of SEQ ID NOs: 2 and 4, seem to be a special technical feature, however, for the reasons discussed above they are not.

The groups are drawn to two different methods of use of antagonist or inhibitors of the DNA methylase of SEQ ID NOs: 2 and 4. 37 C. F. R. §1.475 does not provide for multiple products or methods within a single application, when the methods lack special corresponding technical feature.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

In addition, the claims are directed to the following patentably distinct species of the claimed invention:

- 1) anti-DNA demethylase antibody,
- 2) double stranded oligonucleotides and antisense oligonucleotides of DNA demethylase, and
- 3) small molecule.

Therefore, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 22 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number



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is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.


If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.

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Patent Examiner

  
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1600